Varenicline (Chantix) Medication to Support Tobacco Cessation

Review for Medical Staff, Naval Hospital Camp Pendleton

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Approved for Distribution and Training via ECOMS

Chantix for Tobacco Cessation

Background and Summary

- Varenicline (Chantix) is a nicotinic receptor partial agonist. It reduces cravings and decreases pleasurable effects of nicotine.
- Approved by FDA in May 2006 for medical support of tobacco cessation. Sole manufacturer is Pfizer.
- Chantix has been available in the military health system since FDA approval, but its use has been inconsistent and controversial across DoD facilities.
- Credentialed providers should prescribe Chantix with great care, and generally as a 2nd-line medical treatment.

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Effectiveness

- Chantix appears to have clinical effectiveness equal to, or greater than, other medical treatments to support tobacco cessation.
- Classic alternative medical treatments include oral bupropion (Zyban or Wellbutrin) and nicotine replacement therapy (nicotine patches or gum, available with or without Rx).
- Nicotine replacement therapies and/or bupropion are generally considered "1st-line" treatments under DoD/VA guidelines, and Chantix is considered a "2nd-line" treatment.

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Safety

- Common side effects of Chantix include:
  - nausea – may be reduced by taking medication with food;
  - sleep disturbance or vivid dreams – may be reduced by altering the timing of, or skipping, evening dose.

- Rare, serious side effects include mental health disturbances. Agitation, depression, and suicidal thoughts/actions have been reported. There were >30 suicide concerns reported among first 5 million users, although true incidence and relatedness to medication use have not been established.

- FDA issued an “Alert” on Chantix and mental health disturbances in early 2008. FDA “Boxed Warning” added

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Military Considerations

- As per FAA and DoD, Chantix is not approved for use in flight status. Aviation professionals, including aircrew and air traffic controllers, must be "grounded" while taking Chantix, and cleared by flight surgeon before return to full duty.
- As per Army guidance, Chantix is not approved for use during deployment. Other services generally follow this guidance in theater.
- Providers should generally avoid Chantix prescribing to anyone with duties that prohibit use of psychotropic medications. These may include submariners, divers, explosive ordnance handlers/drivers, and others.

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Prescribing Guidance

- Only credentialed providers should prescribe Chantix.
- The same provider should see patients for monthly follow-up.
- Initial encounter requires adequate time for interview and record review.
- Review all tobacco cessation support options.
- Establish motivation to quit and quit date with patient.
- Encourage use of formal Tobacco Cessation support class. Several options exist, including classes at NHCP (POC is Julius Phillips at 760-725-1002). Classes are not required, but strongly encouraged.

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Prescribing Guidance (continued)

- If Chantix is prescribed, document counsel on all precautions, and provide patient hand-out. Ensure patient understanding that urgent care is required for any mental health challenges.

- Document that patient is not in flight status or planning deployment while on Chantix.

- Avoid use in pregnant or breastfeeding women. Document counsel on this issue. (Chantix is a Pregnancy-Category-C drug, that is unlikely to be approved for use in pregnancy. Chantix may be passed in breast milk, and may not be safe for infants.)

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Prescribing Guidance (continued)

- Prescribe with extreme caution to patients with a history of mental health challenges or mental health medications.

- Although no diagnoses or prescriptions are absolute contraindications to Chantix, consultation with the treating mental health care provider is strongly advised.

Note:

- Mental health side effects in Chantix users are possible without prior mental health diagnoses.
- Mental health side effects in Chantix users are possible after many weeks of use without initial problems.

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Prescribing Guidance (continued)

- Chantix is dispensed in easy-to-follow blister packs. The 1st month "starter pack" graduates initial dose up from 0.5 mg daily to 1 mg twice/daily. Subsequent "continuation packs" include monthly supplies of 1 mg twice/daily.
- Plan to see patients at least monthly while on Chantix. Each month supply should be given without refills to ensure follow-up.
- Recommended duration of treatment is 3 months. Patients may self-taper off Chantix at the end of 3rd pack.
- If patients are successful in quitting tobacco, but having difficulty tapering off Chantix, consider continuing treatment for one month at a time, up to 12 months.

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Prescribing Guidance (continued)

- Advise patients to take Chantix with food.
- Advise patients to take Chantix as directed. If doses are missed, however, do not take make-up doses. In general, do not take more than 1 pill at a time, or more than 2 pills in a day.
- Advise patients never to share Chantix pills with friends or family.
- Advise patients to avoid tobacco* or nicotine-containing products while on Chantix.

** Nicotine exposure on Chantix will likely cause nausea and headache. Most providers recommend patients try to smoke few cigarettes in first week of Chantix; negative*

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Resources

Prescribing providers must have access to:

- USPHS. Clinical Practice Guidelines: Treating Tobacco Use and Dependence, last updated May 2008.
- BUMED Tobacco Cessation Action Team (TCAT) Toolbox http://www.nmcphc.med.navy.mil/bumed/tcat/
- Patient hand-out, “Chantix – What you need to know”
- DoD Medication Safety Notice on Chantix, May 2008
- Provider information on Chantix (Pfizer), updated July 2009